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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
TWUMEY, P	
ART UNIT	**PAPER NUMBER**
1804	

DATE MAILED: 01/17/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/485,943	Applicant(s) Friedman, et al.
	Examiner Patrick Twomey, Ph.D.	Group Art Unit 1804

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire --0-- month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-53* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-53* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-16 and 27-31, drawn to DNA, oligonucleotides, and transfected cells, classified in Class 536, subclass 23.1.

Group II. Claims 17-26, drawn to polypeptides and polymers, classified in Class 530, subclass 399.

Group III. Claims 32-38, drawn to antibodies and methods of preparing them, classified in Class 530, subclass 389.2.

Group IV. Claims 39-43, drawn to methods of measuring ob polypeptide in vitro, classified in Class 435, subclass 7.1.

Group V. Claims 44-45, drawn to methods of using antisense and ribozymes, classified in Class 514, subclass 44.

Group VI. Claims 46-49, drawn to pharmaceutical compositions of proteins and methods of using them, classified in Class 424, subclass 98.1.

Group VII. Claim 50, drawn to gene therapy, classified in Class 514, subclass 44.

Group VIII. Claims 51-53, drawn to an ob antagonist, classified in various classes and subclasses depending on the molecule used.

This application contains claims directed to the following patentably distinct species of the claimed invention:

a) an antibody that neutralizes ob;

b) a fragment of ob polypeptide;

c) a small molecule antagonist of ob.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 51-53 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or

identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of group I and the inventions of groups II-IV and VI are mutually exclusive and independent inventions. Group I is drawn to isolated DNA, probes, expression vectors and cells containing them, whereas groups II-IV are drawn to polypeptides, antibodies and methods of measuring polypeptides. The DNA and cells of group I are not required for the methods of groups II-IV and VI and the methods of groups II-IV and VI cannot be practiced with the compositions of group I. Furthermore, the proteins of groups II-IV and VI are materially different and distinct from the nucleic acids and cells of group I.

The inventions of group I are related to the inventions of groups V and VII as product and process of use, however, the DNA of group I can also be used for in vitro hybridization assays.

The inventions of group I and the inventions of group VIII are mutually exclusive and independent inventions. Group I is drawn to isolated DNA and cells, whereas group VIII is drawn to

antagonists of ob polypeptide and methods of using them. The inventions of group I are not required for the methods of group VIII and the DNA and cells of group I are materially different and distinct from the proteins of group VIII.

The inventions of groups II-IV and the inventions of groups V and VII are mutually exclusive and independent inventions. Groups II-VI are drawn to proteins and methods of using them, whereas groups V and VII are drawn to nucleic acids and methods of using them. The compositions and methods of groups II-IV are not needed for the methods of groups V and VII, and the compositions and methods of groups V and VII are not needed for the methods of groups II-IV.

The inventions of group II are related to the inventions of group III as intermediate and final product, however, the ob polypeptide of group II can also be used as a therapeutic composition.

The inventions of group II and the inventions of group IV are mutually exclusive and independent inventions. Group II is drawn to ob polypeptides, whereas group IV is drawn to a method of measuring ob polypeptides in vitro using antibodies. The polypeptide of group II is not needed to practice the method of group IV.

The inventions of groups II and VI are related as intermediate and final product, however the polypeptide of group II can also be used to produce antibodies.

The inventions of group II and the inventions of group VIII are mutually exclusive and independent inventions. Group II is drawn to ob polypeptides whereas group VIII is drawn to antagonists of ob polypeptide.

The inventions of group III are related to the inventions of group IV as product and process of using, however the antibodies of group III can also be used as a therapeutic composition.

The inventions of groups III and VI are mutually exclusive and independent inventions. The antibodies of group III are not needed for the methods and compositions of group VI, and the pharmaceutical compositions of group VI are not required to prepare the antibodies of group III.

The inventions of group III are related to the inventions of group VIII as product and process of using, however, the antibodies of group III can also be used in in vitro testing.

The inventions of group IV and the inventions of groups VI and VIII are mutually exclusive and independent inventions. The methods of measuring ob polypeptide of group IV are not required for the compositions and methods of groups VI and VIII, and the compositions and methods of groups VI and VIII are not required for the methods of group IV.

The inventions of group V and the inventions of groups VI and VIII are mutually exclusive and independent inventions. The methods of using antisense and ribozymes of group V are not required for the protein compositions and methods of groups VI and VIII.

The inventions of groups V and VII are mutually exclusive and independent inventions. The antisense and ribozyme inventions of group V are not required for the gene expression methods of group VII, and the methods of group VII are not required for the methods of group V.

The inventions of group VI and the inventions of group VII are mutually exclusive and independent inventions. The protein compositions of group VI are not needed for the gene expression methods of group VII, and the gene expression methods of group VII are not needed for the protein therapies of group VI.

The inventions of groups VI and VIII are mutually exclusive and independent inventions. The ob protein compositions of group VI are not needed for the methods of group VIII, and the methods and antagonist compositions of group VIII are not needed for the methods and compositions of group VI.

The inventions of groups VII and VIII are mutually exclusive and independent. The gene therapy methods of group VII are not needed for the methods of using protein antagonists of group

VIII, nor are the methods and protein compositions of group VIII needed for the methods of group VII.

Because these inventions are distinct for the reasons given above and because they have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Paul Fehlner on 12/20/96 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Twomey, Ph.D. whose telephone number is (703) 305-7022. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached on (703) 308-3153. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Patrick Twomey, Ph.D.
December 24, 1996

Deborah Crouch
DEBORAH CROUCH
PATENT EXAMINER
GROUP 1800